K072538

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510(k) SUMMARY

United Medical Systems (DE), Inc.'s Piezolith 3000 Triple-Focus Extracorporeal Shock Wave Lithotripsy System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

United Medical Systems (DE), Inc.
1500 West Park Drive
Suite 390
Westborough, MA 01581
Phone: (508) 870-6565
Fax: (508) 870-0682

Contact Person: Joseph Pelletiere, Director of Operations

Date Prepared: September 6, 2007

Name of Device and Name/Address of Sponsor

Piezolith 3000 Triple-Focus Extracorporeal Shock Wave Lithotripsy System

United Medical Systems (DE), Inc.
1500 West Park Drive
Suite 390
Westborough, MA 01581

Common or Usual Name/Classification Name

Extracorporeal Shock Wave Lithotripsy System/ Urological Lithotripter

Predicate Devices

United Medical Systems (DE), Inc.'s Piezolith 3000 Lithotripter (K032958)
Karl Storz Modulith Lithotripter (K010340, K012482, K011700)
Direx Systems Corporation Integra (K053640, K062147)

Intended Use / Indications for Use

The Piezolith 3000 Triple-Focus is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Technological Characteristics

The Piezolith 3000 Triple-Focus consists of: (1) a shock wave generator, which includes an adjustable therapy head/coupling mechanism mounted on an articulating arm or (when X-ray imaging is used) mounted to a swivel slide on C-arm (LITHOARM); (2) a control console (device trolley); (3) ultrasound imaging system for localization; (4) an optional X-ray system for localization; and (5) a treatment table.

Performance Data

Bench and clinical testing was performed using the Piezolith 3000 Triple-Focus. In addition, the modified device was tested according to the following standards: IEC 60601-1 (1988) (including Amendment 1(1991) and Amendment 2 (1995)); IEC 60601-1-1 (2000) with Amendment 1, 1995; IEC 60601-1-2 (2001); IEC 60601-2-36 (1997); IEC 61846 (1998). In all instances, the Piezolith 3000 Triple-Focus functioned as intended and the results observed were as expected.

Substantial Equivalence

The Piezolith 3000 Triple-Focus is as safe and effective as the Piezolith 3000 (K032958), the Karl Storz Modulith Lithotripter (K010340, K012482, K011700), and the Direx Systems Corporation Integra (K053640, K062147). The Piezolith 3000 Triple-Focus has the same intended uses/indications for use, and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the Piezolith 3000 Triple-Focus and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Piezolith 3000 Triple-Focus is as safe and effective as the predicate devices. Thus, the Piezolith 3000 Triple-Focus is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 30 2008

United Medical Systems, Inc.
c/o Mr. Jeffrey K. Shapiro
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
WASHINGTON DC 20005

Re: K072538
Trade/Device Name: Piezolith 3000 Triple-Focus Extracorporeal Shock Wave Lithotripsy System
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: January 23, 2008
Received: January 23, 2008

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072538

Device Name: Piezolith 3000 Triple-Focus Lithotripter

Indications for Use:

The Piezolith 3000 Triple-Focus is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072538

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